



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35  
5197  
Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
FAX: (513) 679-2772

February 23, 2001

WARNING LETTER  
CIN-WL 6158-01

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. David H. Harris  
Harris Livestock  
1030 Ashland County Road 30-A  
Ashland, Ohio 44805

Dear Mr. Harris:

The U. S. Food and Drug Administration (FDA) was informed by the USDA that tissue from a cow identified with the dealer tag number: 31FDO 184 and slaughtered on or around September 25, 2000, was found to contain an illegal drug residue. The USDA laboratory's analytical report #392816, shows that the kidney tissue of the referenced animal contained 1.62 ppm Penicillin. The established tolerance level for this drug in cows intended for slaughter as human food is 0.05 ppm. This cow was offered for slaughter as food in violation of Sections 402 (a)(2)(C) (ii), and 402 (a)(4). An investigation at your dairy operation conducted by our investigators on December 1, 2000, and December 29, 2000, determined that this cow belonged to you. This investigation also documented that you medicate animals with the prescription drug, Excenel (Ceftiofur Hydrochloride), without a prescription or guidance from a veterinarian. This is a violation of Section 501 (a)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

A food is adulterated under Section 402 (a)(2)(C) (ii) of the Act, if it contains a new animal drug which is unsafe within the meaning of Section 512 and Section 402 (a)(4) if the food has been held under insanitary conditions whereby it may have been rendered injurious to health. As it applies in this instance, "insanitary conditions", refers to your lack of records for medicated animals under your control and for those animals which you personally medicate. A drug is adulterated under Section 501 (a)(5) if it is administered in a manner other than in accordance with the directions specified in the labeling, i.e., without a prescription, thereby making it unsafe within the meaning of Section 512(a)(1)(B).

You also failed to inform your hauler of the medicated status of this animal and you neglected to take reasonable steps to insure that the animal was properly disposed of. Consequently, an animal bearing possibly harmful drug residues was slaughtered for food. The FD&C Act is a strict liability law, which requires anyone in a responsible position with the authority and power to prevent the violation, to exercise the necessary care to prevent the violation.

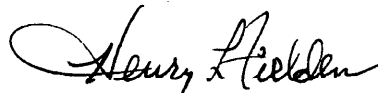
It is not necessary for you to have personally shipped an adulterated animal in interstate commerce to violate the Food, Drug & Cosmetic Act. The fact that you caused the adulteration of an animal, which was slaughtered for food after shipment in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

Failure to promptly implement adequate corrections may result in further regulatory action without further notice. This action could include seizure and/or injunction. At the conclusion of our investigation, you were given a copy of the FDA's "Inspectional Observations", FDA form 483. On this form, our investigators noted that you promised to correct the violations cited in this letter.

Please notify this office within fifteen (15) working days of the receipt of this letter of the specific steps that you have taken to correct the noted violations. Your response should include an explanation of each step being taken to prevent the recurrence of similar violations in future. If your corrective action(s) can not be completed within 15 working days, please state the reason for the delay, and the time frame within which the necessary corrections will be completed.

Your response should be directed to the U. S. Food and Drug Administration, Cincinnati District Office, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, ATTN: David C. Radle, Tissue Residue Monitor.

Sincerely,

A handwritten signature in black ink, appearing to read "Henry L. Fielden", written in a cursive style.

Henry L. Fielden  
District Director  
Cincinnati District